K092141

5. 510(k) Summary

MAR 1 0 2010

3M ESPE
Dental Products

3M Center
St. Paul, MN 55144-1000
651 733 1110

3M ESPE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter..... 3M Company
3M ESPE Dental Products
3M Center, Bldg. 275-2W-08
St. Paul, MN 55144-1000 USA
Establishment Registration Number: 2110898

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Date Summary was Prepared..... 5 March 2010

Trade Name..... Vanish™ Varnish, 5% Sodium Fluoride White Varnish

Common Name(s)..... Cavity Varnish

Recommended Classification..... Cavity Varnish
(21 CFR 872.3260)

Predicate Devices:
3M™ ESPE™ Vanish™ Varnish
Enamel Pro® Varnish

Description and Technology Equivalence:

Vanish™ Varnish, 5% Sodium Fluoride Varnish is classified as Cavity Varnish (21 C.F.R§872.3260) because it is a device that provides relief from tooth surface hypersensitivity when applied to enamel and dentin surfaces by forming a film that facilitates occlusion of compromised surfaces including open dentinal tubules.

Vanish Varnish is a topically applied, flavored cavity varnish containing sodium fluoride and calcium phosphate in a rosin based preparation. The varnish is an insoluble viscous liquid that forms a film on tooth surfaces.

The chemical composition is identical, with the exception of tri-calcium phosphate (TCP), to predicate fluoride containing rosin based cavity varnish devices that have been in use for decades. More recently, varnishes have incorporated calcium and phosphate. Published literature indicates that the incorporation of calcium based ingredients into oral care products aid in mineral deposition. The data provided in this 510(k) submission shows that the composition is safe based on the biocompatibility assessment conducted based on ISO10993 and ISO 7405.

This product is equivalent to current varnishes in properties, intended use and composition. Results provided in the submission confirm the equivalent to the predicate devices with common indications.

Indications for Use:

- Treatment of hypersensitive teeth
- Use on exposed dentin and root sensitivity
- Under temporary restoratives and cements where post-operative sensitivity is of concern

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 1 0 2010

Shari L. Myszka, Ph. D.
Regulatory Affairs Specialist
3M ESPE Dental Products
3M Center, Building 275-2W-08
St. Paul, Minnesota 55144

Re: K092141
Trade/Device Name: Vanish™ Varnish, 5% Sodium Fluoride White Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: February 17, 2010
Received: February 19, 2010

Dear Dr. Myszka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Vanish™ Varnish, 5% Sodium Fluoride White Varnish

Indications for Use:

- Treatment of hypersensitive teeth
- Use on exposed dentin and root sensitivity
- Under temporary restoratives and cements where post-operative sensitivity is of concern

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Betz DDS for M. K. P. Mahan

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092141